

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FI | LING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|------------|-------------|----------------------|---------------------|------------------|
| 08/948,149 | 10/09/1997 | | BRIAN M. FENDLY | P1053R2 | 6683 |
| 24510 | 7590 | 10/10/2003 | | EXAM | INER |
| | | RUDNICK & V | SWARTZ, RODNEY P | | |
| STEVEN B I 1200 NINET | | TREET, NW | ART UNIT | PAPER NUMBER | |
| | | 20036-2412 | 1645 | | |

DATE MAILED: 10/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. Applicant(s) | | |
|---|---|---|--|
| Advisory Action | 08/948,149 | FENDLY ET AL. | |
| · | Examiner | Art Unit | |
| | Rodney P. Swartz, Ph.D. | 1645 | |
| The MAILING DATE of this communication appe | ears on the cover sheet with the c | correspondence address | |
| THE REPLY FILED 25July2003 FAILS TO PLACE THIS Therefore, further action by the applicant is required to a final rejection under 37 CFR 1.113 may only be either: (1 condition for allowance; (2) a timely filed Notice of Appea Examination (RCE) in compliance with 37 CFR 1.114. | void abandonment of this applica) a timely filed amendment whicl | ation. A proper reply to a places the application in | |
| PERIOD FOR RE | EPLY [check either a) or b)] | | |
| a) The period for reply expiresmonths from the mailir | • | | |
| b) The period for reply expires on: (1) the mailing date of this a no event, however, will the statutory period for reply expire ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS 706.07(f). | later than SIX MONTHS from the mailing | g date of the final rejection. | |
| Extensions of time may be obtained under 37 CFR 1.136(a). The fee have been filed is the date for purposes of determining the period of fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of (2) as set forth in (b) above, if checked. Any reply received by the Offitimely filed, may reduce any earned patent term adjustment. See 37 C | of extension and the corresponding amo the shortened statutory period for reply ce later than three months after the mail | unt of the fee. The appropriate extension originally set in the final Office action; or | |
| 1. A Notice of Appeal was filed on <u>25July2003</u> . Appel 37 CFR 1.192(a), or any extension thereof (37 CFI | | | |
| 2. The proposed amendment(s) will not be entered be | ecause: | | |
| (a) they raise new issues that would require further | er consideration and/or search (s | see NOTE below); | |
| (b) they raise the issue of new matter (see Note b | pelow); | • | |
| (c) they are not deemed to place the application i issues for appeal; and/or | n better form for appeal by mate | rially reducing or simplifying the | |
| (d) they present additional claims without cancel NOTE: | ing a corresponding number of fi | nally rejected claims. | |
| 3. Applicant's reply has overcome the following reject | tion(s): | | |
| 4. Newly proposed or amended claim(s) would canceling the non-allowable claim(s). | | parate, timely filed amendment | |
| 5. ☑ The a) ☐ affidavit, b) ☐ exhibit, or c) ☑ request for application in condition for allowance because: see | | dered but does NOT place the | |
| 6. The affidavit or exhibit will NOT be considered becaraised by the Examiner in the final rejection. | ause it is not directed SOLELY t | o issues which were newly | |
| 7. For purposes of Appeal, the proposed amendment explanation of how the new or amended claims we | | | |
| The status of the claim(s) is (or will be) as follows: | | | |
| Claim(s) allowed: none. | | | |
| Claim(s) objected to: <u>none</u> . | | | |
| Claim(s) rejected: <u>28-40,42-62</u> . | | | |
| Claim(s) withdrawn from consideration: | | | |
| 8. \square The proposed drawing correction filed on is | a) ☐ approved or b) ☐ disapp | roved by the Examiner. | |
| 9. Note the attached Information Disclosure Statemen | nt(s)(PTO-1449) Paper No(s) | | |
| 10. ☐ Other: | | | |
| | | | |

Application/Control Number: 08/948,149

Art Unit: 1645

DETAILED ACTION

1. Applicants' Response to Final Office Action, received 25July2003, paper#39, is acknowledged.

2. Currently, claims 28-40 and 42-62 are pending and under consideration.

Rejections Maintained

3. The rejection of claims 28-31, 37-38, 40, 56, and 57 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991) is maintained for reasons of record.

Applicants argue that the antibodies utilized in the references are not publicly available due to the stringent requirements of the Materials Transfer Agreement of Genentech.

The examiner has considered applicants' arguments, but does not find them persuasive. Following discussions of the Materials Transfer Agreement with Brian Stanton, Quality

Assurance Specialist, the MTA, while placing some restrictions on the use of the antibodies of Genentech, does not preclude anyone in the public from obtaining the materials as long as they agree to said restrictions. Therefor, the antibodies are deemed to be publicly available at the time of the filing of the instant application.

4. The rejection of claims 28-31, 37-38 and 40 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993) is maintained for reasons of record.

Applicants argue that that the antibodies utilized in the references are not publicly available due to the stringent requirements of the Materials Transfer Agreement of Genentech.

The examiner has considered applicants' arguments, but does not find them persuasive.

Following discussions of the Materials Transfer Agreement with Brian Stanton, Quality

Application/Control Number: 08/948,149

Art Unit: 1645

Assurance Specialist, the MTA, while placing some restrictions on the use of the antibodies of Genentech, does not preclude anyone in the public from obtaining the materials as long as they agree to said restrictions. Therefor, the antibodies are deemed to be publicly available at the time of the filing of the instant application.

5. The rejection of claims 32-36, 39, and 58 under 35 U.S.C. 103(a) as being unpatentable Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991), or Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993), in view of Fendly et al (*Cancer Research*, 50:1550-1558, 1990), Deshane et al (*J. Invest. Med.*, 43(Suppl 2):328A, 1995), and further in view of Senter et al (U.S. Pat. No. 4,975,278) is maintained for reasons of record.

Applicants argue that that the antibodies utilized in the references are not publicly available due to the stringent requirements of the Materials Transfer Agreement of Genentech.

The examiner has considered applicants' arguments, but does not find them persuasive. Following discussions of the Materials Transfer Agreement with Brian Stanton, Quality

Assurance Specialist, the MTA, while placing some restrictions on the use of the antibodies of Genentech, does not preclude anyone in the public from obtaining the materials as long as they agree to said restrictions. Therefor, the antibodies are deemed to be publicly available at the time of the filing of the instant application.

6. The rejection of claims 42-55 and 59-62 under 35 U.S.C. 103(a) as being unpatentable Shepard et al (*J. Clinb. Immunol.*, 11(3):117-127, 1991), in view of Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993) and Fendly et al (*Cancer Research*, 50:1550-1558, 1990), and further in view of Deshane et al (*J. Invest. Med.*, 43(Suppl 2):328A, 1995) and Senter et al (U.S. Pat. No. 4,975,278) is maintained for reasons of record.

Art Unit: 1645

Applicants argue that that the antibodies utilized in the references are not publicly available due to the stringent requirements of the Materials Transfer Agreement of Genentech.

The examiner has considered applicants' arguments, but does not find them persuasive. Following discussions of the Materials Transfer Agreement with Brian Stanton, Quality

Assurance Specialist, the MTA, while placing some restrictions on the use of the antibodies of Genentech, does not preclude anyone in the public from obtaining the materials as long as they agree to said restrictions. Therefor, the antibodies are deemed to be publicly available at the time of the filing of the instant application.

Conclusion

- 7. No claims are allowed.
- 8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)398-2035

PRIMARY EXAMINER
Art Unit 1645

October 9, 2003